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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,224	05/02/2006	Satoshi Miyata	KOD182B.001APC	7803

20995 7590 01/23/2008  
KNOBBE MARTENS OLSON & BEAR LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER
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EBRAHIM, NABILA G

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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01/23/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartere@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/550,224	<b>Applicant(s)</b> MIYATA ET AL.	
	<b>Examiner</b> Nabila G. Ebrahim	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

The office action dated 8/29/07 has been herein vacated for not considering the preliminary amendments.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 6-10, and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bombardelli et al EP0300282 (Bombardelli). The reference is provided by Applicant in Information Disclosure Statement dated 6/15/06.

Bombardelli teaches topical pharmaceutical or cosmetic compositions having eutrophic and cutis protecting activities, based on complexes of silybin, silydianin, silychristin or mixtures thereof with vegetal or synthetic phospholipids.

The reference discloses that the complexes, or those obtainable from Silybum marianum extracts, may be advantageously used in topical pharmaceutical or cosmetic compositions, useful to counteract degenerative and aging phenomena (page 2, line 9+). The silymarin is used in an amount encompassed by the range recited in claim 6 of 0.7-2.00% (see preparations, page 1 and 2).

2. Claims 17, 19, 20 rejected under 35 U.S.C. 102(b) as being anticipated by A. Benaiges et al. Study of the refirming effect of a plant complex, International Journal of Cosmetic Science Volume 20 Issue 4 Page 223-233, August 1998 (Benaiges).

Benaiges disclosed a study of the refirming effect of a plant complex and teaches that one way to prevent such a loss of elasticity is to use active ingredients that are able to inhibit elastase enzymes. A plant complex was prepared using the following plants: lady's thistle (*Silybum marianum* GAERTN), alchemilla or yarrow (*Alchemilla vulgaris* L.), horsetail (*Equisetum arvense* L.) as well as germinated seeds (*Glycine soja* Siebold and Zucc., *Triticum vulgare* Vilars, *Medicago sativa* L., *Raphanus sativus* L.). The complex was standardized to give the corresponding active principles, silybin, tannins, silicon and peptides, respectively, and in vitro enzymatic tests were carried out to establish its ability to inhibit elastase. The study of enzymatic inhibition was carried out using two enzymes: (1) porcine pancreatic elastase (PPE), and (2) human leukocyte elastase (HLE). The results showed that the plant complex presents non-competitive inhibition in the order of 41.0% against PPE and 50.0% against HLE. An in vivo test was made alongside the in vitro test using an SEM 474 Cutometer (Courage & Khazaka) to study the elasticity of the skin, and positive effects were obtained when applying a cosmetic formulation containing 5% of the plant complex. Image analysis of duplicates of the cutaneous surface, before and after treatment began with a product containing 5% of plant complex and showed that wrinkles were decreased by 36.7% (abstract). Note that HLE is the enzyme responsible for breaking elastin and since the effect of the

potanical extract inhibited the effect of HLE by 50%, it is expected that the increase of elastin is doubled as required by claim 20.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et al EP0300282 (Bombardelli) and Benaiges et al. Study of the refirming effect of a plant complex, International Journal of Cosmetic Science Volume 20 Issue 4 Page 223-233, August 1998 in view of Sekimoto US 6814958 (Sekimoto).

Bombardelli and Benaiges were discussed above.

Bombardelli and Benaiges do not teach the use of the use of silymarin in food products.

Sekimoto teaches food composition comprising silymarin (abstract and claims 1, 5, 7 and 9). Note that the intended use of the claimed composition has not been given patentable weight, because the prior art compositions would be at least capable of performing said use.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Bombardelli's composition in the method disclosed by Benaiges and produce it as a food as Sekimoto teaches to facilitate the intake of the silymarin as some people prefer to use active ingredients over pharmaceutical dosage forms. The expected results would be a topical cosmetic or food preparation comprising silymarin, which is used for anti-aging purposes.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

Application/Control Number:  
10/550,224  
Art Unit: 1618

Page 6

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim  
12/14/07



SHEENI PADMANABHAN  
SENIOR PATENT EXAMINER